Atty Dkt. No.: UCAL-131CON3

USSN: 10/735,140

REMARKS

FORMAL MATTERS:

Claims 39-41 are pending.

Claims 1-38 are canceled without prejudice.

DOUBLE PATENTING REJECTION

Claims 39-41 were rejected under the judicially created doctrine of obviousness-type double patenting. Without acquiescing to the validity of the rejection applicants have attached hereto a Terminal Disclaimer. The attached Terminal Disclaimer is with respect to U.S. Patent 6,720,355 as well as co-pending application 10/641,687 and is submitted only to expedite prosecution. In view of the attached Terminal Disclaimer the rejection has been rendered moot.

REJECTIONS UNDER §112, ¶1

Claims 39-41 were rejected under 35 U.S.C. §112, first paragraph. The rejection is respectfully traversed and its reconsideration and withdrawal respectfully requested.

The Examiner indicates that the specification is enabling with respect to contacting prions with SDS and acid at temperatures in a range of 37°C to 140°C. However, the rejection argues that the specification does not provide enablement with respect to the identification of what a non-infectious prion is.

Applicants point out that the claim is directed to contacting PrP protein with the specifically recited composition at a particular pH range and particular temperature range. By carrying out the method the PrP protein is rendered completely non-infectious within two hours or less. Data such as shown within Figure 11 indicate that when the pH is within the claimed range of 2.5 to 4.5 an SDS is added. The PrP protein is completely denatured. There is no evidence that denatured PrP protein is in any way infective. Accordingly, the method claimed has been demonstrated as being effective.

The Deslys patent is directed to a method for purifying PrP proteins away from a biological sample. The method taught by Deslys involves purifying abnormal PrP proteins such as prions away by incubating a sample for a period of time with a buffer which includes a surfactant. A suspension is then added to the buffered solution to form a microemulsion or microsuspension. Centrifugation of the suspension is then carried out to form a residue and that residue is solubilized in a buffer.

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Example 2 of Deslys refers to treatment of a bovine brain sample. Accordingly, applicants are unclear as to how the Deslys reference and specifically Example 2 of this reference demonstrates, in any way, that the claimed invention is not operative. Applicants demonstrated the ability of cationic detergents combined with peracetic acid or acetic acid within a certain pH range to render infectious prions completely non-infectious within the temperature range of 15°C to 140°C.

By referring to Example 17 on page 91 and Figure 11 it can be seen that SDS does have an effect at relatively low concentrations on denaturing PrP protein at a pH range of 10 or less. However, applicants recognize that with low concentrations of SDS there is some remaining indication of PrP protein being present when the pH is in the range of 5 to 9. When the pH drops below 4.5 there is no indication of there being any PrP protein present. This demonstrates that any infective protein present within the treated samples has been denatured and rendered completely non-infective. In view of such reconsideration and withdrawal of the rejection is respectfully requested.

Because this application is related to application Serial Nos. 10/735,454 and 10/641,687, the Examiner is also respectfully referred to these applications.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

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The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCAL-131CON3.

Respectfully submitted,

BOZICEVIC, FIELD & FRANCIS LLP

Date: $\int \int \int A d$

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Enclosure(s): Terminal Disclaimer

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